

**LIBELED:** 6-19-58, S. Dist. N.Y.

**CHARGE:** 501(c)—the strength of the article, while held for sale, differed from that which it purported and was represented to possess since the article contained less vitamin B<sub>1</sub> and less niacinamide than declared; 502(a)—the label statement "Each containing \* \* \* Thiamin hydrochloride (B<sub>1</sub>) 3.0 mgs. \* \* \* Niacinamide 30.0 mgs." was false and misleading as applied to a product containing less than the declared amounts of thiamin hydrochloride and niacinamide, and the label statement "Caution: To be dispensed only by or on the prescription of a physician" was false and misleading as applied to a product that was not restricted to dispensing on a physician's prescription; and 502(f) (1)—the labeling of the article failed to bear adequate directions for use since no dosage statement was given and no indications for use were stated.

**DISPOSITION:** 7-18-58. Default—destruction.

**5712. Creme ointment and suntan lotions.** (F.D.C. No. 41902. S. Nos. 1-480/1 P.)

**QUANTITY:** 2,204 ctns. of *creme ointment*, 643 6-oz. btls.; and 242 4-oz. btls., and 27 combination sets of *suntan lotions* at Fort Lauderdale, Fla., in possession of Aloe Creme Laboratories, Inc.

**SHIPPED:** 1-29-58, from Milwaukee, Wis., by Kolmar Laboratories, Inc.

**LABEL IN PART:** (Ctn.) "Alo-Creme With Lanolin Ointment \* \* \* Ingredients: Contains 50% or more fresh "gel" from the Aloe Vera leaf, protected in a specially prepared base containing lanolin. Contains no anaesthetic drugs. Distributed by Aloe Creme Laboratories, Inc., Ft. Lauderdale, Florida"; (btl.) "Fashion Tan by Aloe Creme \* \* \* Contains the "gel" of Florida's famous Aloe Vera plant"; (btl.) "After Tan by Aloe Creme \* \* \* contains the "gel" of Florida's famous Aloe Vera Plant in a super rich lanolin base."

**ACCOMPANYING LABELING:** Leaflets entitled "Sunburn vs. Suntan" and "Aloe-Creme Ointment."

**RESULTS OF INVESTIGATION:** The leaflets entitled "Aloe-Creme Ointment" and the ctns. for the ointment were prepared locally.

**LIBELED:** 7-21-58, S. Dist. Fla.

**CHARGE:** 502(a)—while held for sale, the labeling of the ointment contained false and misleading representation that the article was an adequate and effective treatment for all burns, skin abrasions, cuts, rashes, itching, dermatitis, skin irritations, hemorrhoids, piles, and bed sores; and 502(f) (2)—the ointment was offered for piles and hemorrhoids, and its labeling failed to bear a warning that the article should not be used in case of rectal bleeding.

502(a)—when shipped and while held for sale, the labeling which accompanied the suntan lotions contained false and misleading representations that the articles were an adequate and effective treatment for preventing skin cancer.

**DISPOSITION:** 11-18-58. Consent—claimed by Aloe Creme Laboratories, Inc., and relabeled.

**5713. Medicated cream, inhalant and rubbing oil, and castile soap.** (F.D.C. No. 41849. S. Nos. 19-177/9 P.)

QUANTITY: 216 1½-oz. jars and 17 4-oz. jars of *medicated cream*, 72 1-oz. btls. of *inhalant and rubbing oil*, and 528 pkgs. of *castile soap* at Denver, Colo., in possession of Charles Van Castle.

SHIPPED: 4-29-58, from Tulsa, Okla.

LABEL IN PART: "Smiling-Feet A Truly Wonderful Medicated Cream with Many Uses, Especially for the Feet. Contains Eucalyptus, Peppermint, Thymol, Menthol, Camphor, Phenol, Lanolin, Glycerine, Salicylic and Benzoic Acid in a Special Cream Base," "Smiling Brand Inhalant & Rubbing Oil \* \* \* Active Ingredients Eucalyptus Oil, Menthol; \* \* \* Peppermint Oil, Thymol, Camphor," and "Sanitary Castile Soap for the Complexion, Skin, Scalp and Toilet."

LIBELED: 6-4-58, Dist. Colo.

CHARGE: 502(f) (1)—The labeling of the articles failed to bear adequate directions for use for the purposes for which they were intended, namely, (*medicated cream*) in the treatment of corns, callouses, bunions, cramps, athlete's foot, any kind of skin trouble or skin disease, blackheads, whiteheads, nervous rash, lines in the face, and pimpled skin, (*inhalant and rubbing oil*) in the treatment of weak eyes or poor vision, sinus trouble, arthritis, and rheumatism, and (*castile soap*) for the prevention of greying hair, falling hair, and baldness, which were the purposes for which the articles were offered orally by Charles Van Castle on 5-5-58 and 5-8-58.

DISPOSITION: 7-29-58. Default—the castile soap was delivered to a Federal institution for its use, and the other articles were destroyed.

**5714. Douche solution.** (F.D.C. No. 41785. S. No. 39-625 P.)

QUANTITY: 578 btls. at Sacramento, Calif.

SHIPPED: 3-1-57, from Norwood Heights, Ohio.

LABEL IN PART: "Feminette A Cleansing, Bacteriostatic Douche Especially Designed to Relieve the Itching and Burning Common in Many Types of Vaginitis, Directions \* \* \* Contains: High Molecular Alkyl Dimethyl Benzyl Ammonium Chloride and Aromatics \* \* \* 8 Fl. Oz."

ACCOMPANYING LABELING: Leaflets entitled "Feminette Douche Solution Is For You."

LIBELED: 5-28-58, N. Dist. Calif.

CHARGE: 502(a)—the labeling of the article, while held for sale, contained false and misleading representations that the article was effective for the relief of itching and burning common in many types of vaginitis; and 502(f) (2)—the labeling of the article failed to warn that the article should not be used more than twice weekly unless directed by a physician.

DISPOSITION: 7-16-58. Default—destruction.

**5715. Royal jelly capsules.** (F.D.C. No. 41918. S. No. 19-785 P.)

QUANTITY: 12 btls. at Perry, Okla., in possession of Monte L. Jones Drug Co.

SHIPPED: 5-16-58 and 5-25-58, from Hollywood, Fla.

LABEL IN PART: "48 Capsules Royal Jelly High Potency 50 mg. \* \* \* Each Capsule contains: 50 mg. Royal Jelly, in a base of wheat germ oil, plus other vegetable oils."

ACCOMPANYING LABELING: A newspaper advertisement which had been printed and circulated in Perry, Okla., and which contained representations concerning the efficacy of royal jelly.